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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,483	12/03/2003	Yoshihito Fukui	034071-002	3993

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BUCHANAN INGERSOLL PC
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EXAMINER	
REIDEL, JESSICA L	
ART UNIT	**PAPER NUMBER**
3766	

DATE MAILED: 02/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/725,483	FUKUI, YOSHIHITO	
	Examiner	Art Unit	
	Jessica L. Reidel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-11 and 13-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-11 and 13-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: _____.

DETAILED ACTION

1. Acknowledgment is made of Applicant's Amendment, which was received by the Office on December 15, 2005. Claim 2 has been cancelled. In regards to Claim 12, which states "Currently Amended", there are no limitations present in the Amended Claims list received on December 15, 2005 (i.e. the claim appears to have been cancelled). The Examiner takes the position that Claim 12 has been cancelled and is prosecuting the Application as such. Currently, Claims 1, 3-11 and 13-23 are active.

Claim Objections

2. Claims 1, and 3 are objected to because of the following informalities: there appears to be typographical errors present in the claims. Specifically the Examiner suggests changing lines 8-9 of Claim 1 from "memory at which is memorized at least one table relating to a plurality of nerve stimulation parameters in response to sensed values by said sensor" to "memory at which is memorized at least one table relating a plurality of nerve stimulation parameters to sensed values by said sensor". In regards to Claim 3, since Applicant is claiming "a plurality of nerve stimulation parameters" the Examiner suggest changing line 2 from "said nerve stimulation parameters" to "said plurality of nerve stimulation parameters" and changing line 3 from "with respect to at least one" to "with respect to at least two" to add clarity and consistency to the claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim. The Examiner prosecutes the Application such that "a blood" is synonymous with "a blood sensor".

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 3, 7-11, 14 and 20-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Kieval et al. (U.S. 6,073,048) (herein Kieval). As to Claims 1 and 20-21, Kieval discloses a method and an implanted pulse generating device, read as a heart treatment equipment 10 for treating a patient (see Kieval Fig. 7 and Abstract) comprising a pair of electrical leads 160a and 160b, preferably including bipolar electrodes 160c and 160d for stimulating right and/or left stellate ganglions (153 and 154) of the vagus nerves or the vagal afferent nerves (i.e. baroreceptors) (see Kieval column 4, lines 10-15 and column 6, lines 6-20) and a lead body 150 and lead body 150' which should contain a sensor for sensing living body information to carry

out the closed-loop feedback embodiments of the invention (see Kieval Abstract, column 5, lines 59-67 and column 7, lines 16-27). In addition Kieval discloses that the heart treatment equipment 10 comprises an implantable pulse generator 140 with a microprocessor, read as a controller (see Kieval column 5, lines 51-60 and column 10, lines 20-26) comprising a nerve stimulation parameter table memory (see Kieval column 8, line 4) at which is memorized at least one table relating a plurality of nerve stimulation parameters to sensed values (i.e. heart rate, pressure etc.) by the sensor (see Kieval column 7, lines 36-55). Kieval also discloses that the heart treatment equipment 10 operates in a closed loop manner where the microprocessor of the IPG 140 controls the nerve stimulation via parameters selected or modulated in response to the output of the sensor (see Kieval Abstract, column 3, lines 43-67 and column 4, lines 1-6).

8. As to Claim 3 and 23, Kieval discloses that the plurality of parameters may be at least one of the rate, pulse width, amplitude, frequency of the stimulation (see Kieval column 7, lines 39-43) and actual timing of the stimulation (see Kieval column 8, lines 19-29).

9. As to Claim 7, Kieval further discloses that the sensor used to modulate the selected parameters of the nerve stimulation may be an activity sensor indicative of whether or not the patient is involved in a period of exercise so as to allow the nerve stimulation to necessarily be decreased (see Kieval column 3, lines 66-67 and column 4, lines 1-4).

10. As to Claim 8, Kieval discloses that the sensor used to modulate the selected parameters of the nerve stimulation may be a pH sensor used on lead 150 to detect the level of lactic acid in venous return blood. It is inherent that lactic acid is a product of cellular respiration (see Kieval column 6, lines 29-51).

11. As to Claim 9, Kieval discloses that the sensor used to modulate the selected parameters of the nerve stimulation may be a blood oxygen sensor (see Kieval column 6, lines 52-55).

12. As to Claim 10, Kieval further discloses that the heart treatment equipment 10 may further comprise a pacemaker for bradycardia support pacing when the heart rate decreases below a predetermine rate (see Kieval Fig. 6 and column 7, lines 50-65).

13. As to Claim 11, Kieval discloses an implanted pulse generating device, read as a heart treatment equipment 10 for treating a patient (see Kieval Fig. 7 and Abstract) comprising a pair of electrical leads 160a and 160b, preferably including bipolar electrodes 160c and 160d for stimulating right and/or left stellate ganglions (153 and 154) of the vagus nerves or the vagal afferent nerves (i.e. baroreceptors) (see Kieval column 4, lines 10-15 and column 6, lines 6-20) and a lead body 150 and lead body 150' which should contain a sensor that may be a heart abnormal detector such as one that indicates an arrhythmia via heart rate or heart sound detection (see Kieval column 4, lines 17-29 and column 7, lines 15-35) to carry out the closed-loop feedback embodiments of the invention (see Kieval Abstract, column 5, lines 59-67 and column 7, lines 16-27). In addition Kieval discloses that the heart treatment equipment 10 comprises an implantable pulse generator 140 with a microprocessor, read as a controller (see Kieval column 5, lines 51-60 and column 10, lines 20-26) comprising a nerve stimulation parameter table memory (see Kieval column 8, line 4) at which is memorized at least one table relating a plurality of nerve stimulation parameters to sensed values (i.e. heart rate, pressure etc.) by the sensor (see Kieval column 7, lines 36-55). Kieval also discloses that the heart treatment equipment 10 operates in a closed loop manner where the microprocessor of the IPG 140

controls the nerve stimulation via parameters selected or modulated in response to the output of the sensor (see Kieval Abstract, column 3, lines 43-67 and column 4, lines 1-6).

14. As to Claim 14, Kieval discloses that the plurality of parameters may be at least one of the rate, pulse width, amplitude, frequency of the stimulation (see Kieval column 7, lines 39-43) and actual timing of the stimulation (see Kieval column 8, lines 19-29).

15. As to Claim 22, Kieval discloses that in one or more intracardiac leads to collect signals 92 such as heart rate, pressure etc. are used in a preferred embodiment of the invention to be fed back into the IPG 91f and 92f which can be used to modulate the stimulation to meet a patient's needs and that such intracardiac signals such as heart rate and pressure are controlled by autonomic nerve activity (see Kieval column 1, lines 39-66 and column 7, lines 16-27).

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. Claims 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kieval in view of Falkenberg (EP 1 142 608 A2). Kieval discloses the claimed invention as discussed above except that the sensor is not specified to be a sensor which detects a ventricular contractility related to one of a QT interval, an intracardiac electrogram area, a pre-ejection period, a stroke volume and a ventricular pressure where the controller stops the nerve stimulation when the ventricular contractility is out of a predetermined range.

Falkenberg, however, teaches cardiac pacing techniques comprising controller 60 that controls various modes of stimulation therapy via commanding control signals to trigger or inhibit stimulation pulses when contractility is out of predetermined range (see Falkenberg Fig. 3 and column 6, lines 30-31 and lines 50-55). Falkenberg also discloses controller 60 determining contractility based on pressure, acceleration or pressure signals received from sensors, or stroke volume (see Falkenberg column 9, lines 56-58). Falkenberg also teaches that vasovagul syncope causes the ventricles to contract much more quickly and vigorously than would otherwise occur in an effort to maintain constant stroke volume (see Falkenberg column 1, lines 1-46). It is inherent or at least obvious to one having ordinary skill in the art that vasovagul synocope is caused by a decrease in vagul nerve activity. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the heart treatment equipment of Kieval in view of Falkenberg to include detecting ventricle contractility related to one of a pre-ejection period, a stroke volume, and ventricle pressure in order to increase the device's ability to determine if administering therapy is necessary, and to program the controller to control the nerve stimulator to stop the generation of the nerve stimulation signal when the ventricle contractility is out of predetermined range to improve the invention.

18. Claims 13 and 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kieval in view of Schwartz (U.S. 5,330,507). As to Claims 13 and 15-18, Kieval discloses the claimed invention as discussed above except that the heart treatment equipment does not further comprise a heart event detector for detecting a heart event coupled to the heart abnormal detector for detecting a tachycardia risk event.

Schwartz, however, discloses a method and apparatus for stimulating the right or left vagus nerve for prevention or interruption of life threatening arrhythmias (see Schwartz Abstract). Schwartz also disclose a heart event detector 104 for detecting a heart event where heart abnormal detector 100 is a risk event detector connected to the heart risk event detector 104 for detecting a tachycardia risk event (see Schwartz Fig. 2 column 2, lines 1-2 and column 6, lines 3-9, lines 19-26, and lines 44-49). Schwartz also discloses that the detected risk event includes an increase of a heart rate (see Schwartz Abstract line 6) or a premature contraction (see Schwartz column 4, line 55) or an early after-depolarization or a delayed after-depolarization (see Schwartz column 4, lines 53-56 and column 6, lines 20-26). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the heart treatment equipment of Kieval in view of Schwartz comprise a heart event detector for detecting a heart event coupled to the heart abnormal detector for detecting a tachycardia risk event for stimulating the right or left vagus nerve for prevention or interruption of life threatening arrhythmias.

19. As to Claim 19, Kieval further discloses that the heart treatment equipment 10 may further comprise a pacemaker for bradycardia support pacing when the heart rate decreases below a predetermine rate (see Kieval Fig. 6 and column 7, lines 50-65).

Response to Arguments

20. Applicant's arguments filed December 15, 2005 in regards to Claim 9 have been fully considered but they are not persuasive. Specifically, Claim 9 states that it is "Currently Amended" but it has not been amended to define what type of sensor is being claimed or what exactly the sensor is sensing.

21. Applicant's arguments with respect to claims 1, 11 and 20 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

22. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Adams et al. (U.S. 2003/0229380) discloses closed-loop nerve stimulation for heart failure therapy.

Gross et al. (U.S. 2003/0045909) discloses a closed-loop vagul nerve stimulation system for treating numerous heart conditions such as atrial fibrillation and heart failure.

Ekwall (U.S. 5,683,427) teaches the use of lookup tables to utilize algorithms and transfer curves within a controller of an electrophysiological stimulator.

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The examiner can normally be reached on Mon-Thurs 7-4:30 and every other Friday 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jessica L. Reidel 02/10/06
Examiner
Art Unit 3766

Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766